UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF PENNSYLVANIA

In re Innocoll Holdings Public Limited Company Securities Litigation CLASS ACTION This Document Relates To: All Actions	Master File: 2:17-cv-00341-GEKP **SECOND AMENDED CLASS ACTION COMPLAINT FOR VIOLATIONS OF THE FEDERAL SECURITIES LAWS** **JURY TRIAL DEMANDED**

Lead Plaintiffs Russel Bleiler, Ashok Chainani, JianMin Huang, and Carl Bayney, and Named Plaintiff Gaurangkumar Patel ("Plaintiffs"), individually and on behalf of all other persons similarly situated, by their undersigned attorneys, for their complaint against Defendants (defined below), allege the following based upon personal knowledge as to themselves and their own acts, and information and belief as to all other matters, based upon, inter alia, the investigation conducted by and through their attorneys, which included, among other things, a review of the Defendants' public statements, conference calls and announcements made by Defendants, United States Securities and Exchange Commission ("SEC") filings, wire and press releases published by and regarding Innocoll Holdings Public Limited Company ("Innocoll" or the "Company"), discussions with former Innocoll employees and other persons with knowledge, consultation with an expert, and information readily obtainable on the Internet. Plaintiffs believe that substantial evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

I. NATURE OF THE ACTION

1. This is a securities class action on behalf of a Class consisting of all persons and entities, other than Defendants and certain others listed in ¶198 below, who purchased or otherwise acquired the publicly traded securities of Innocoll between July 25, 2014, and December 29, 2016, both dates inclusive, (the "Class Period"), including in public offerings closing on or around July 25, 2014, April 23, 2015, and June 17, 2016, seeking to recover damages caused by Defendants' violations of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (the "Exchange Act") and Rule 10b-5 promulgated thereunder.

2. On December 29, 2016, after the close of trading, Innocoll announced that the United States Food & Drug Administration ("FDA") had transmitted a refusal to file letter. The

Company's application for its most promising, development-stage commercial product, XaraColl, was so deficient that the FDA refused to accept the filing and to perform a substantive review. Such letters are rare. Defendants had concealed from investors the substantial risk that the FDA would find that XaraColl was a drug/device combination, requiring approval of both the drug and the device. According to Innocoll, the FDA refused to consider the XaraColl filing precisely because the Company had sought approval only for the drug and not for the drug/device combination.

3. Innocoll is a small biotechnology company established in 1997 to develop and commercialize medical sponges, films, powders, and other medical products based on its patented collagen technologies. None of the products the Company has commercialized have succeeded.

4. In 2014, the Innocoll product closest to approval was XaraColl, a collagen sponge implanted into the body after an operation to deliver a local anesthetic, bupivacaine, over time. Innocoll claims that XaraColl provides pain relief for longer than an injection and is bioresorbable, meaning that it naturally is absorbed into the body and need not be removed in a later procedure.

5. Innocoll conducted its initial public offering ("IPO") in July 2014, raising less cash than it had sought. A later offering in mid-2015 failed to raise enough money to take Innocoll's products, XaraColl and Cogenzia, through the completion of their clinical trials and the filing of XaraColl's new drug application ("NDA"), which Defendants claimed they would file in late 2016. Again in mid-2016, weeks after it announced positive Phase 3 clinical trial results for XaraColl, Innocoll floated a third public offering. Days later, it significantly

downsized the offering because the mere announcement of the offering caused Innocoll's stock price to fall. This dearth of cash had severe consequences that Defendants hid from investors.

6. During the Class Period, Defendants misleadingly told investors that the FDA had approved its XaraColl clinical trials and that Innocoll had conducted them by the book. Defendants boasted that, with green lit trials, FDA approval of XaraColl was all but guaranteed. The Company's cash crunch, however, prevented it from adequately funding its operations. In turn, this caused Defendants to cut corners on XaraColl's clinical trials and NDA, imperiling its chances for XaraColl's approval.

7. The FDA regulates drugs and devices. "Combination products" contain both a drug and a device. The FDA receives hundreds of combination product applications annually and has regulations for when applications must seek approval for combination products. Companies seeking approval (dubbed "sponsors" in FDA jargon) of combination products must obtain approval of both the drug ***and*** the device components. Because XaraColl was a combination product, regulations required Innocoll not only to perform drug trials, but to perform a pharmacokinetic study and various non-clinical studies to establish that the collagen sponge—the device component of XaraColl—was safe and effective.

8. Desperate to save scarce capital, unbeknownst to investors Defendants saved $10 million by avoiding the pharmacokinetic and other non-clinical studies to establish that the collagen sponge was safe and effective. Defendants misled investors about the facts they concealed and the risks Innocoll faced. Defendants repeatedly told investors, beginning with the IPO and continuing through to the very end of the Class Period, that Innocoll had twice met with the FDA formally. Defendants misleadingly suggested that the FDA had "approved" and "deemed [] acceptable" XaraColl's pathway to FDA approval at these meetings. Defendants

further represented that there were "no gating issues" to approval, other than Phase 3 clinical trials for XaraColl, and that in their opinion "approval is [] not in question."

9. Defendants knew that there was a substantial risk that the FDA would find that XaraColl was a combination product. Defendants titled the XaraColl patent application that Innocoll prosecuted both before and throughout the Class Period "a drug delivery device," referring to XaraColl as a "drug delivery device" no fewer than 47 times. Defendant Zook was well aware of the patent and its contents, having specifically referred to its prosecution during prepared remarks on his very first conference call as Innocoll's CEO.

10. Indeed, on eight separate occasions Innocoll sought approval for its collagen products as ***devices***. And the FDA has published guidance that a transdermal patch to deliver drugs through the skin to the blood stream is a combination product. As XaraColl is, like a transdermal patch, a drug delivery device that employs its structure (an implanted sponge) to deliver a drug through the tissue to the nerves, it is plain that it is a drug-device combination product.

11. Moreover, Defendants had a motive to conceal deficiencies in XaraColl's clinical trials, as they were seeking – with some success – to fund Innocoll's operations or pursue an exit strategy by trading on their promise that XaraColl would be successful. Innocoll sold $40 million of its shares weeks after Defendants stated that with positive Phase 3 clinical trials, approval was all but guaranteed. And from March 2016 through December 2016, Innocoll sought to sell the European and U.S. rights to XaraColl, and Defendants even sought to sell Innocoll itself. Had Defendants disclosed the deficiencies in XaraColl's clinical trial and NDA, they never could have pursued any of these exit options.

12. Innocoll filed its XaraColl NDA in October 2016, failing to seek approval for its device component.

13. On December 30, 2016, in response to Defendants' announcement of the FDA's refusal to file letter, Innocoll's stock price fell over 61%, causing damages to investors.

II. JURISDICTION AND VENUE

14. The claims asserted herein arise under Sections 10(b) and 20(a) of the Exchange Act (15 U.S.C. §§78j(b) and 78t(a)) and Rule 10b-5 promulgated thereunder by the SEC (17 C.F.R. § 240.10b-5).

15. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §1331 and Section 27 of the Exchange Act (15 U.S.C. §78aa).

16. Venue is proper in this Judicial District pursuant to 28 U.S.C. §1391(b) and Section 27 of the Exchange Act (15 U.S.C. §78aa(c)) as the Company's U.S. headquarters are located in this judicial district.

17. In connection with the acts, transactions, and conduct alleged herein, Defendants directly and indirectly used the means and instrumentalities of interstate commerce, including the United States mail, interstate telephone communications, and the facilities of a national securities exchange.

III. RELEVANT PERSONS

18. Plaintiffs Gaurangkumar Patel, Russel Bleiler, Ashok Chainani, JianMin Huang, and Carl Bayney, as set forth in their PSLRA Certifications which were previously filed and are incorporated by reference herein, purchased Innocoll securities at artificially inflated prices during the Class Period and were damaged thereby.

19. Defendant Innocoll is a specialty pharmaceutical company which develops late-stage products that use its proprietary collagen technologies. Throughout the Class Period, its principal executive offices were located in Monksland, Athlone, Co. Roscommon, Ireland, and its U.S. headquarters were in this District at 3803 West Chester Pike, Newtown Square, PA 19073.

20. Innocoll began the Class Period as Innocoll AG, a German Company. Then, on March 16, 2016, Innocoll AG was "merged" into Innocoll Holdings plc, in a transaction that changed Innocoll's domicile to Ireland but had no substantial effect on its operations or ownership. Under SEC rules, Innocoll Holdings plc was deemed a successor to Innocoll AG. Innocoll Holdings plc kept the same trading symbol as Innocoll AG, and also inherited Innocoll AG's active shelf registration statement. Before March 16, 2016, Innocoll AG's American Depository Shares ("ADSs") were traded on the NASDAQ under ticker INNL. After March 16, 2016, Innocoll Holdings plc's common shares were traded on the NASDAQ under ticker INNL.

21. Defendant Anthony P. Zook has been Innocoll's CEO since December 8, 2014. Defendant Zook has over 30 years of experience in the pharmaceutical industry. He held several executive positions with pharmaceutical giant AstraZeneca, including President and Chief Executive Officer of its North American division, which accounted for more than ten billion dollars in annual sales during his tenure. During the Class Period, he sat on the Boards of

Directors of several biotechnology companies, including AltheRx, Inhibikase, and Rib-X Pharmaceuticals.

22. Defendant Dr. Lesley Russell served as Innocoll's Chief Medical Officer ("CMO") between April 20, 2016 and October 2017. According to a press release issued by Innocoll that day, Defendant Russell "has extensive experience managing the development of pharmaceuticals and biologics across a wide range of therapeutic areas, dosage forms and formulations on a global scale." Defendant Russell served as the Chief Operating Officer and Chief Medical Officer of TetraLogic Pharmaceuticals, where she advanced that company's lead candidate into Phase 2 clinical trials. She has experience managing staff responsible for regulatory strategy development.

23. Non-party Michael Myers served as Innocoll's CEO between June 2003 and December 2014. Myers has more than 27 years of industry experience in the drug delivery and specialty pharmaceuticals sector. Between 1987 and 1995, he served as Elan Corporation's Head of Pharmaceutical Development, leaving to take up a position as President, Pharmaceutical Division at Fuisz Technologies.

24. Non-party David Prior has served as Innocoll's Executive Vice President of Global Regulatory Affairs since 2008. He is listed as an inventor on Innocoll's patent for the collagen sponge used in XaraColl. Like Myers, he worked for Elan Corporation and Fuisz Technologies.

25. Defendants Zook and Russell are the "Individual Defendants."

26. Innocoll is liable for the acts of the Individual Defendants and its employees under the doctrine of *respondeat superior* and common law principles of agency because all of the wrongful acts complained of herein were carried out within the scope of their employment.

27. The *scienter* of the Individual Defendants and other employees and agents of the Company is similarly imputed to Innocoll under *respondeat superior* and agency principles.

28. Defendants Innocoll and the Individual Defendants are the "Defendants."

IV. DEFENDANTS KNEW OR RECKLESSLY DISREGARDED THE SUBSTANTIAL RISK THAT XARACOLL WAS A DRUG-DEVICE COMBINATION

A. The Steps Necessary To Obtain FDA Approval of Combination Products Are Well Understood

29. XaraColl is Innocoll's main product. According to Innocoll, it is a patented collagen sponge that is implanted near the wound site during surgery and releases a local anesthetic, bupivacaine, over time to provide sustained postsurgical pain relief. It provides longer-lasting relief than a simple injection at the time of the surgery. The collagen sponge is bioresorbable, meaning that it dissolves by itself over time and is absorbed into the body.

30. The FDA is the federal government agency responsible for approval of drugs, medical devices, and drug/device combinations, including Innocoll's products. The Federal Food, Drug, and Cosmetic Act (the "Act"), 21 U.S.C. 9 § 301 *et seq*., governs the regulation and safety of, among other things, drugs and medical devices in the United States.

31. The FDA's Center for Drug Evaluation and Research ("Drug Center") is designated the lead Center for regulating drugs to ensure their safety and effectiveness. The mission of the Drug Center is to ensure that drugs marketed in this country are safe and effective. The Drug Center is the largest of FDA's six centers responsible for monitoring drugs, biologics, and medical devices.

32. The medical device counterpart to the Drug Center is the Center for Devices and Radiological Health ("Device Center"). The Device Center is designated the lead center for the FDA for regulating medical devices to ensure their safety and effectiveness.

33. The FDA established the Office of Combination Products ("Combination Office") to develop guidance and regulations governing combination products, to assign an FDA center to have primary jurisdiction for review of both combination and non-combination products where the jurisdiction is unclear or in dispute, and to ensure timely and effective premarket review of combination products by overseeing and coordinating reviews involving more than one agency center. The Combination Office answers questions regarding combination products. Sponsors may request informal advice or a formal Request for Designation, binding on the FDA, which determines which FDA medical product center has primary jurisdiction for a combination product. The Combination Office was established in 2012.

34. FDA regulations make it clear that in the first instance, determining whether a product is a drug, device, or combination product is the company's responsibility. On the FDA website for medical devices, in the section for regulatory assistance, under the header titled "How to Study and Market Your Device", the FDA warns companies that:

> If your product is a combination product - a medical device plus another FDA-regulated product (e.g. drug, biologics, etc.), you should contact FDA's Office of Combination Product [] by e-mail []. Based on your product's primary mode of action, [Combination Office] will tell you which FDA Center that you need to contact in order to market your product.

35. The same page indicates that "[y]ou must follow the steps below prior to marketing a medical device in the United States."

36. A combination product is assigned to an Agency Center or alternative organizational component that will have primary jurisdiction for its premarket review and

regulation. Under section 503(g)(1) of the Food and Drug Act, assignment to a center with primary jurisdiction, or a lead center, is based on a determination of the "primary mode of action" of the combination product, defined as the single mode of action of a combination product that provides the most important therapeutic action of the combination product. For example, if the primary mode of action of a drug-device combination product is attributable to the drug product, the Center responsible for premarket review of that drug product would have primary jurisdiction for the combination product. The Center with primary jurisdiction will then consult with the other relevant Centers, a formal process called a "Consult." If the application is successful, the Consult and its results will be disclosed in the publicly-filed approval.

37. Depending upon the type of combination product, its approval, clearance or licensure may be obtained through submission of a single marketing application, or through separate marketing applications for the individual constituent parts of the combination product. The FDA may determine that two marketing applications are necessary. For example, on occasion, a sponsor will submit an application for a combination product where one of the individual constituent parts is already approved for another use and the labeling of the new product will need to be changed to reflect its new intended use in the combination product. In such a case, the FDA may determine that two applications are necessary if the labeling of the already approved product is subject to legal requirements different from those that will apply to the combination product.

38. Combination products are hardly niche products. Around 300 application product applications are filed every year, with 357 submitted in FY 2016.[1]

[1] FDA – Office of Combination Products Performance Report to Congress ("2016 Performance Report"), at 11, available at (continued on next page)

39. To introduce a new drug into the U.S. market, a company must submit to the FDA an NDA. It is the responsibility of the sponsor seeking to market a drug to test it and submit adequate evidence to the FDA that it is safe and effective. A team of Drug Center physicians, statisticians, chemists, pharmacologists, and other scientists will review the sponsor's NDA.

40. An NDA must provide enough information to permit FDA reviewers to determine whether the drug is safe and effective in its proposed uses, whether the benefits of the drug outweigh the risks, whether the proposed labeling is appropriate, and whether the manufacturing methods are adequate to preserve the drug's strength, quality, and purity. The documentation required in an NDA is supposed to tell the drug's whole story, including the drug's ingredients, clinical tests results, including animal studies, how the drug behaves in the body, and manufacturing, packaging, and marketing information.

41. Obtaining approval of a drug typically requires three sets of clinical trials. Phase 1 trials establish that the drug is safe to be studied and establish dosage. Phase 2 trials are meant to establish clinical efficacy. But Phase 2 trials are typically not large enough to statistically demonstrate that the drug is safe and effective. Phase 3 trials are pivotal trials. They are designed to be large enough to show that the drug is effective, safe and does not have adverse reactions. Each phase has a distinct timeline – Phase 1 typically lasts a few months, Phase 2 a few months to two years, and Phase 3 one to four years.

42. Obtaining approval for a device requires, at a minimum, a demonstration of safety and effectiveness. Devices posing low to moderate risks, such as a manual toothbrush, are referred to as Class I devices and face only general controls. Devices posing moderate to high risk, such as a non-invasive blood pressure monitor, are subject to general and special controls.

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https://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/CombinationProducts/UCM606678.pdf.

43. Because the FDA had never approved a device employing Innocoll's collagen sponge to release a drug over time, at a minimum, Innocoll was required to present clinical and nonclinical data showing the safety and effectiveness impact of the collagen sponge. 21 C.F.R. §807.87(g). The FDA required a clinical pharmacokinetic study and non-clinical toxicology and biocompatibility studies.

B. The FDA's door is open to companies seeking guidance

44. The FDA's mission includes "advancing the public health by helping to speed innovations that make medical products more effective, safer, and more affordable." If a company has discovered a medical product that would be beneficial to patients and is safe and effective, the FDA wants to help sponsors prove it so that the sponsor can sell the product, improving patients' lives.

45. Accordingly, sponsors that are unsure whether their products are drugs, devices, or combination products may ask questions of the FDA informally by telephone or email, and may also seek formal meetings with the FDA to answer questions they may have about drug or device approval. The FDA has issued guidance on seeking its assistance titled "Formal Meetings Between the FDA and Sponsors of Applicants" (the "Meeting Guidance").[2]

46. The FDA will answer all of a sponsor's questions to make the pathway to approval as clear as possible. But the FDA's role is not to divine what issues may arise that may bar approval. Instead, as the Meeting Guidance shows, it is up to the FDA to answer the sponsors' questions, and up to the sponsors to identify questions for the FDA to which they need answers:

[2] References are to the version issued in May 2009, which was the latest official version at the time of Innocoll's End of Phase 2 and July 2015 Meetings with the FDA.

a. The company's meeting request must include among other things a brief statement of the purpose and objectives of the requested meeting, a proposed agenda (including a brief background on the issues underlying it), a list of proposed questions (including their purpose). Meeting Guidance, at 4-5.

b. The request "should define the specific areas of input needed from [the FDA division]." Meeting Guidance, at 5.

c. The meeting package submitted by the company to the FDA must include among other things a brief statement summarizing the purpose of the meeting, a proposed agenda, and a list of the questions for discussion with a summary for each question to explain the need or context.

47. Thus, sponsors cannot depend on the FDA to identify all potential obstacles to approval in a formal meeting. Indeed, prior to a meeting, the FDA suggests that sponsors identify FDA professionals (by name, if known, or discipline, if not), requesting that those professionals attend the meeting. Meeting Guidance, at 4-5. Thus, if Innocoll sought to ensure that a professional from the Device Center would review XaraColl's pathway to approval and flag any issues at a formal meeting, it was Innocoll's responsibility to request the Device Center's assistance.

C. Innocoll Has More Than A Decade's Experience Obtaining Approval of Its Collagen Products As Devices

48. Collagen is the main component of connective tissues in animal bodies. It accounts for about 30% of the proteins in the human body.

49. Collagen's structure consists of amino acids which are wound together to form elongated fibrils.

50. Collagen has minor uses as an adhesive and a nutritional supplement. But its primary use is in medicine, where it is used as a structural component in tissue recovery, wound care, bone grafts, and the like. But because it is bioresorbable, it is also increasingly being used as a drug delivery device.

51. Innocoll has had limited success developing and commercializing complex collagen-based medical products. By March 31, 2014, shortly before its IPO, Innocoll had an accumulated deficit of €90.8 million, and its then current liabilities exceeded its current assets by €6.9 million. Innocoll's revenues were approximately €3.5 million and €4.3 million in 2013 and 2012, respectively, while it incurred operating losses of €6.9 million and €6.4 million, respectively.

52. At the time, Innocoll had two major product candidates in its development pipeline: XaraColl and Cogenzia, for the treatment of diabetic foot infections.

53. The initial filing of the XaraColl patent came two years after Innocoll first filed for FDA approval of a collagen sponge device, for CollaGUARD.

54. Innocoll has a decade of prior experience of bringing collagen products to the FDA for approval. All of these collagen products were classified as devices with the FDA. In fact, Innocoll used this long experience as a selling point to investors. For example, on a November 4, 2016 conference call to discuss the results of Cogenzia's clinical trials and XaraColl's NDA application, Charles F. Katzer, Innocoll's Vice President, Global Supply and Procurement, stated that "with our experience in the extraction and purification of Type 1 collagen of over 20 years specifically in the bupivacaine collagen formulation for XaraColl here, we have a strong stability profile exceeding most. We have the benefit of 20 years' experience in the product."

55. Zook was even more adamant. On his inaugural conference call as Innocoll's CEO, Zook boasted that "our ***core strength*** at Innocoll is found within our deep knowledge of collagen-based drug delivery, and this has enabled the team at Innocoll to take existing medications like bupivacaine [] and significantly improve their overall effectiveness."[3]

56. From 2006 through 2014, Innocoll obtained FDA approval to sell eight separate devices. All of these devices were made from collagen. Innocoll presented them as medical devices to the FDA under the following names (year submitted in parentheses): CollaGUARD (2006), Collieva (2008), Collagen Sponge (2010), Collexa (2010), Collacare Dental (2011), Collagen Powder (2011), Procoll (2012), and Collacare Dental (2014).

D. Xaracoll's Patents Show That Defendants Knew Xaracoll Was A Drug-Device Combination

57. Xaracoll's patents, which Innocoll prosecuted both before and throughout the Class Period, repeatedly identify XaraColl as a "drug delivery device" and make clear that XaraColl's device aspects are crucial to its safety and effectiveness.

58. On March 28, 2008, Innocoll filed a patent to protect the collagen sponge used in XaraColl (Application 12/058,298) (the "U.S. Application").

59. Innocoll titled the U.S. Application "[a] drug delivery device for providing local analgesia, local anesthesia or nerve blockade." On the U.S. Application, Innocoll's claims include claimed that XaraColl is "[a] ***drug delivery device*** for providing local analgesia, local anesthesia or nerve blockade at a site in a human or animal in need thereof, the device comprising a fibrillar collagen matrix; and at least one drug substance selected [...]" Claim No. 1. The U.S. Application's claims further include "[t]he drug delivery device of claim 1, wherein the

[3] Emphasis is added unless otherwise noted.

at least one drug substance is an amino amide anesthetic selected from the group comprising Bupivacaine [...]". Claim No. 4. Indeed, Innocoll stated that the collagen sponge is a "drug delivery device" no fewer than ***47 times*** in the 13 pages of the U.S. Application. Thus, by virtue of their having submitted and or reviewed the U.S. Application, Defendants knew that XaraColl is a combination product consisting of a drug (bupivacaine) and a device (the collagen sponge).

60. The U.S. Application does not claim any uses other than to deliver local pain relief through a substance released from a collagen sponge.

61. The U.S. Application was granted on October 11, 2011, as patent US 8,034,368 B2 ("'368 Patent").

62. Each of Innocoll's annual reports and each of the registration statements and prospectuses it filed with the SEC on or before the Class Period boasted that one of Innocoll's competitive advantages was its intellectual property. Each time, Innocoll specifically mentioned that it protected XaraColl through a patent issued in 2011 – i.e., the '368 Patent.

63. The '368 Patent lists Myers, Innocoll's CEO, as one of the inventors.

64. Innocoll continued to prosecute the '368 Patent during the Class Period.

65. On March 19, 2015, Innocoll submitted an application to the FDA to reissue the 368 Patent to add additional prior art references. At the time, Defendant Zook was Innocoll's CEO.

66. Innocoll's 20-F for the year ended December 31, 2014 ("2014 20-F"), which Defendant Zook signed, referenced Innocoll's application to reissue the '368 Patent. The 2014 20-F acknowledged that there was a risk that the U.S. patent office would not reissue the '368 Patent and that, if so, Innocoll would suffer material harm.

67. On a conference call to discuss Innocoll's Q4 2014 earnings taking place on March 19, 2015 (the "Q4 2014 Earnings Call"), Zook stated that Innocoll "recently submitted a petition to reissue the US patent directed to XaraColl [i.e., the '368 Patent] for the purpose of submitting prior art references identified in the corresponding European applications." Zook also acknowledged that Innocoll "did not submit these prior art references to the US Patent and Trademark Office during the prosecution of the US patent. Thus they weren't part of the record for the issued US patent." Thus, Zook was familiar with the details of the '368 Patent.

68. In addition, Zook acknowledged that Innocoll was seeking to have additional claims added to the reissued patent, stating that:

> In addition, the reissue process will allow us to pursue additional claims. For example claims within the scope of the original issued claims, ***but more tailored to our currently proposed XaraColl product.*** We don't believe these prior art references should have any substantial impact on the original issued claims.

69. Thus, Innocoll's request to reissue the '368 patent was not a mere formality. Instead, Innocoll sought to expand the patent.

70. On September 2, 2016, Innocoll filed a corresponding European patent application, Application No. 16154811.0 (the "European Application").

71. The European Application likewise was titled "A Drug Delivery Device ..."

72. Like the U.S. Application, the European Application's claims include "[a] drug delivery device suitable providing local analgesia, local anesthesia or nerve blockade at a site in a human or animal in need thereof, ***the device comprising a fibrillar collagen matrix***; and at least one drug substance[...]" Claim No. 1. Thus, the European Application likewise shows that XaraColl is a combination product consisting of a device (the collagen sponge) and a drug (bupivacaine).

73. The European Patent Application refers to XaraColl as a "drug delivery device" ***54 times***.

74. On November 6, 2009, Innocoll filed a U.S. patent application for CollaRx, the collagen sponge used in XaraColl (Application 13/128,057) (the "CollaRx Application"). The CollaRx Application listed two senior Innocoll employees as inventors: David Prior and Joan Fitzpatrick, Innocoll's then-Executive Vice President of Research & Development.

75. CollaRx is not a standalone product. Rather, it is the collagen sponge used in XaraColl. It has not been approved by the FDA for any purpose.

76. The CollaRx Application acknowledged in its prior art section that "[m]any of today's products aimed at localised [sic] delivery ***are device-drug combinations***." CollaRx Application ¶17.

77. The CollaRx Application cited classic examples of drug-device combinations such as infusion pumps, medicated stents, and bone cement containing an antibiotic. *Id.* ¶17.

78. The CollaRx Application contended, however, that because existing drug-device combinations were not bioresorbable, they sometimes caused infections or swelled and exerted pressure on neural structures. As Innocoll stated in the CollaRx Application, CollaRx aimed to provide a "drug delivery implant" that addressed the deficiencies in existing drug-device combinations.

79. The CollaRx Application makes clear that the clinical effectiveness and safety of XaraColl similarly depends on certain extremely specific characteristics of the collagen sponge. These necessary characteristics include the collagen sponge's viscosity, the method of its sterilization, the method of its preparation by first immersing the sponge in a saline solution and then inserting an acidic solution. All of these characteristics were discovered empirically.

a. The viscosity of the liquid within the collagen sponge is critical to the clinical effectiveness of XaraColl. *Id.* ¶24. Specifically, the collagen sponge must have a viscosity of greater than 100mPas when a 25 ml of 2mM of hydrochloric acid at a pH of less than 3.5 and a temperature of 30°C plus or minus 0.5°C. *Id.* ¶23.

b. The method of sterilization is critical to the clinical effectiveness of XaraColl. Pharmacokynetic studies show that unless a particular method of sterilization is used, the rate of release of the drug undesirably has two peaks. ¶27. This result is "surprising[]". *Id.* The particular method of irradiating the collagen sponge to sterilize it eliminates this undesirable double peak effect, allowing for extended clinical efficacy. *Id.* ¶28. This result, too, is "surprising[]". *Id.* The CollaRx Application's claims specify the method of sterilization. *Id.* Claims 12, 16.

c. The method of preparation is critical to the clinical effectiveness of XaraColl. The method of preparation must create cross-links between layers of collagen sponge. *Id.* ¶28. To prepare XaraColl, a 70 mg collagen sponge must be immersed in 50 ml of saline solution for 10 minutes at 37° C to reduce volume by at least 30%. *Id.* ¶33. After immersion, the collagen sponge must be mixed with an acidic solution to achieve a pH of about 4.5 (between 3.6 and 4.9), at a concentration of about 5.6 mg/ml (between 2.5 and 11.2), and then lyophilized (flash frozen) as a collagen sponge. *Id.* ¶36. After insertion of the drug, the collagen sponge must have a pH of 3.9 plus or minus 0.3. *Id.* ¶37.

d. Ultimately, all these specifications are necessary for XaraColl's efficacy. First, a properly-structured collagen sponge lasts at least 50% longer than other collagen implants. *Id.* ¶26. And second, because CollaRx is porous, it collapses as soon as

it becomes wet – unlike other collagen – thus allowing it to be left behind in the body. *Id.* ¶79.

80. Thus, the CollaRx Application's extensive and detailed specifications make clear that the collagen sponge is no off-the-shelf product. Instead, the collagen sponge used in XaraColl was an extremely complex made-to-order device manufactured through a customized and empirically developed set of steps. It is plain that the FDA would require that CollaRx, the collagen sponge used in XaraColl, be approved as a device and that, moreover, because it was so complicated and specific, Defendants could not be certain that the FDA would approve it.

81. Nor is the collagen sponge a mere excipient (i.e., an inactive ingredient). The FDA maintains a list of excipients and their uses.[4] Collagen is only an excipient when it is applied as a gel on the body or when it is ingested as a time-release capsule. The FDA has never found that collagen is an excipient when it forms a structure that releases a drug over time.

82. FDA publications make crystal clear precisely how the FDA will treat XaraColl. In 1991, the Device Center and the Drug Center entered into the Intercenter Agreement Between the Center for Drug Evaluation and Research and the Center for Devices and Radiological Health (the "Intercenter Agreement"), signed in 1991. The Intercenter Agreement is prominently displayed on the FDA's website,[5] cross-referenced in a critical section of the FDA's website,[6] and discussed in the Code of Federal Regulations, 21 C.F.R. § 3.5.

[4] Available for download at https://www.fda.gov/Drugs/InformationOnDrugs/ucm113978.htm
[5] *See* https://www.fda.gov/CombinationProducts/JurisdictionalInformation/ucm121177.htm.
[6] *See* Special Considerations in the Medical Devices section of the FDA's Website, https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/ucm134578.htm

83. The Intercenter Agreement (1) identifies types of products that will be treated as drug/device combinations, and (2) states whether the sponsor should apply to the Device Center or the Drug Center.

84. The Intercenter Agreement shows, with examples, that XaraColl is a drug/device combination.

85. The Intercenter Agreement explains that combination products include "device[s] with primary purpose of delivering or aiding in the delivery of a drug and distributed containing a drug (i.e., 'prefilled delivery system[s]')." In 2016 alone, 67 applications were filed for pre-filled drug delivery devices/systems. 2016 Performance Report, at 13.

86. The Intercenter Agreement provides, as an example of such a combination product, a transdermal patch. Transdermal patches deliver a drug with which they have been impregnated – ***exactly*** like XaraColl.

87. The Intercenter Agreement also provides: "***A device that serves as a container for a drug*** or a device that is a drug delivery system attached to the drug container where the drug is present in the container ***is a combination product***".

88. XaraColl and CollaRx's patents explain that the collagen sponge is, at the very least, a drug delivery device "that serves as a container for a drug."

89. Accordingly, the Intercenter Agreement provides that XaraColl is a combination product.

90. Accordingly, Zook and Russell were well aware or were reckless in not knowing that there was a substantial risk that the FDA would follow the Intercenter Agreement and find that XaraColl is a drug-device combination.

E. Innocoll Employees Who Reported Directly to Zook Discussed that XaraColl had Device Components

91. Sources inside Innocoll confirm that Defendants understood that XaraColl was a combination product, requiring separate FDA approval for the device component.

92. Innocoll employed a Medical Affairs consultant from July 2015 through to November 2015 ("Medical Affairs Consultant"). The Medical Affairs Consultant's responsibilities included ensuring that XaraColl's promotional materials were medically and technically accurate. He reported directly to Innocoll's then-chief medical officer ("CMO"), Dr. James Tursi, until Tursi left Innocoll in September 2015. The Medical Affairs Consultant also worked closely with David Prior.

93. Tursi was CMO of Innocoll from March 2015 through September 2015. CMO is a senior officer position, and Tursi reported directly to Defendant Zook. Dr. Tursi has more than twenty years' medical experience, including four years as CMO of Auxilium Pharmaceuticals, which was acquired for $2.6 billion.

94. David Prior was employed at Innocoll in senior positions since December 2004, and served as Executive Vice President – Clinical, Regulatory and Scientific Affairs from 2008 through the end of the Class Period. Prior was listed as one of six members of Innocoll's executive management team in its SEC filings and on its website during the Class Period.

95. The Medical Affairs Consultant reports that both Prior and Tursi specifically told him during his tenure that XaraColl was a device. Indeed, according to the Medical Affairs Consultant, he "was told in the U.S. that it would be considered as a device. That's what I remember being told."

V. DEFENDANTS MADE FALSE AND MISLEADING STATEMENTS DURING THE CLASS PERIOD

96. On July 24, 2014, Innocoll filed an Amended Registration (the "IPO Registration Statement") on Form F-1/A for shares to be sold in its IPO. Myers signed the IPO Registration Statement.

97. The IPO Registration Statement was declared effective on July 25, 2014.

98. Pursuant to the IPO Registration Statement, Innocoll sold 6,500,000 ADSs, with net proceeds to it of $54.4 million, before expenses.

99. The IPO Registration Statement provided, in relevant part:

> XaraColl has been studied in one Phase 1 and four completed Phase 2 clinical trials enrolling approximately 184 patients, including 103 patients in two Phase 2 trials in hernia repair at doses of 100 mg and 200 mg of bupivacaine. Results from both trials demonstrated that XaraColl reduces both pain intensity and opioid consumption with the 200 mg dose resulting in an overall greater combined effect at 48 hours. XaraColl-treated patients in the 100 mg dose trial experienced significantly less pain through 24 hours (44% reduction; p = 0.001), 48 hours (37% reduction; p = 0.012) and 72 hours (34% reduction; p = 0.030). In our subsequent 200 mg dose trial, XaraColl demonstrated a statistically significant reduction in opioid consumption through 24 and 48 hours (44% reduction at 24 hours, p = 0.004, and 36% reduction at 48 hours, p = 0.042), and demonstrated a statistical trend in reduction in pain intensity through 24 hours (p = 0.080). When we apply the Silverman method, a validated statistical analysis that integrates the patient's pain intensity with opioid consumption, to these results, the 100 mg dose trial demonstrated a statistically significant reduction at 24 hours (p = 0.013) and the 200 mg dose trial demonstrated a statistically significant reduction at both 24 and 48 hours (p = 0.005 and p = 0.039, respectively) as well as a statistical trend through 72 hours (p = 0.07). ***The primary endpoint in our two planned Phase 3 trials will use this integrated Silverman method assessment of pain and opioid consumption, as agreed to with the FDA in our end-of-Phase 2 meeting.***

100. The IPO Registration Statement also provided:

> Develop XaraColl for treatment of post-operative pain. We plan to initiate our two planned Phase 3 trials for XaraColl in the second half of 2014, ***as established with the FDA at our end-of-Phase 2 meeting***.

101. The IPO Registration Statement similarly provided:

> Thus we believe that by applying the Silverman method and integrating both pain intensity and opioid consumption into a single endpoint rather than assessing a single parameter alone, we can generate a more meaningful interpretation of trial results. Following our end-of-Phase 2 meeting, ***the FDA agreed to permit us to pursue such integrated end point in our Phase 3 trial***.

102. The emphasized statements were misleading because there was a substantial risk that the FDA would find that XaraColl is a drug-delivery combination product, thus requiring additional tests for approval, including a pharmacokinetic clinical study and other non-clinical studies The purpose of FDA meetings is for the sponsor to raise, discuss and resolve any issues that could lead to denial of approval. Therefore, by stating that Innocoll had held a XaraColl Post Phase 2 meeting with the FDA, and that the FDA had agreed to a plan for XaraColl, Defendants conveyed that it had resolved all issues in the design of clinical trials they were aware of that could lead to denial of approval. In fact, Innocoll and its officers knew that XaraColl had device components which there was a substantial risk would require separate approval from the FDA following separate clinical trials and other studies. Yet as Defendants admitted to an analyst following the end of the Class Period, Defendants never discussed what trials and/or studies would be required for approval of XaraColl's device components with the FDA. *See* ¶151, below. Therefore, Defendants' statements gave the misleading impression that the FDA had deemed that all that was required for approval was for XaraColl to meet its Phase 3 clinical trial endpoints, when in fact, there was a substantial risk that the FDA would not file or approve XaraColl's NDA because it would require Innocoll to show that XaraColl's device components were safe and effective through additional studies.

103. On December 8, 2014, Defendant Zook was appointed as Innocoll's CEO.

104. On March 19, 2015, Innocoll filed its 20-F for the year ended December 31, 2014 (the "2014 20-F"), which was signed by Defendant Zook. Separately, Defendant Zook executed a certification under the Sarbanes-Oxley Act of 2002 ("SOX"), certifying that:

> 2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report
>
> [...]
>
> 4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
>
> (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared; [and]
>
> [...]
>
> (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; []

105. The 2014 20-F provided, in relevant part:

> XaraColl has been studied in one Phase 1 and four completed Phase 2 clinical trials enrolling approximately 184 patients, including 103 patients in two Phase 2 trials in hernia repair at doses of 100 mg and 200 mg of bupivacaine. Results from both trials demonstrated that XaraColl reduces both pain intensity and opioid consumption with the 200 mg dose resulting in an overall greater combined effect at 48 hours. XaraColl-treated patients in the 100 mg dose trial experienced significantly less pain through 24 hours (44% reduction; $p = 0.001$), 48 hours (37% reduction; $p = 0.012$) and 72 hours (34% reduction; $p = 0.030$). In our subsequent 200 mg dose trial, XaraColl demonstrated a statistically significant reduction in opioid consumption through 24 and 48 hours (44% reduction at 24

> hours, p = 0.004, and 36% reduction at 48 hours, p = 0.042), and demonstrated a statistical trend in reduction in pain intensity through 24 hours (p = 0.080). When we apply the Silverman method, a validated statistical analysis that integrates the patient's pain intensity with opioid consumption, to these results, the 100 mg dose trial demonstrated a statistically significant reduction at 24 hours (p = 0.013) and the 200 mg dose trial demonstrated a statistically significant reduction at both 24 and 48 hours (p = 0.005 and p = 0.039, respectively) as well as a statistical trend through 72 hours (p = 0.07). These results are indicative of a clear dose-related response. ***The primary endpoint in our two planned Phase 3 trials will use this integrated Silverman method assessment of pain and opioid consumption, as agreed to with the FDA in our end-of-Phase 2 meeting.*** [] We plan to approach the FDA to gain its approval to the change in our study protocol and, subject to this approval, plan to commence testing XaraColl in the third quarter of 2015, ***with pivotal data anticipated in early 2016. We expect to file an NDA for XaraColl in 2016.***

106. The 2014 20-F also provided:

> Thus we believe that by applying the Silverman method and integrating both pain intensity and opioid consumption into a single endpoint rather than assessing a single parameter alone, we can generate a more meaningful interpretation of trial results. Following our end-of-Phase 2 meeting, ***the FDA agreed to permit us to pursue such integrated end point in our Phase 3 trial***.

107. The emphasized statements were misleading because there was a substantial risk that the FDA would find that XaraColl is a drug-delivery combination product, thus requiring additional tests for approval, including a pharmacokinetic clinical study and other non-clinical studies. The purpose of FDA meetings is for the sponsor to raise, discuss and resolve any issues that could lead to denial of approval. Therefore, by stating that Innocoll had held a XaraColl Post Phase 2 meeting with the FDA, and that the FDA had agreed to a plan for XaraColl, Defendants conveyed that it had resolved all issues in the design of clinical trials they were aware of that could lead to denial of approval. In fact, Innocoll and its officers knew that XaraColl had device components which there was a substantial risk would require separate approval from the FDA following separate clinical trials and other studies. Yet as Defendants admitted to an analyst following the end of the Class Period, Defendants never discussed what trials and/or studies

would be required for approval of XaraColl's device components with the FDA. *See* ¶151, below. Therefore, Defendants' statements gave the misleading impression that the FDA had deemed that all that was required for approval was for XaraColl to meet its Phase 3 clinical trial endpoints, when in fact, there was a substantial risk that the FDA would not file or approve XaraColl's NDA because it would require Innocoll to show that XaraColl's device components were safe and effective through additional studies.

108. On April 23, 2015, Innocoll filed a Registration Statement on Form F-1/A (the "April 2015 Registration Statement") in connection with a secondary offering of 3,321,669 ADSs. Of these, 1,999,690 consisted of ADSs sold by Innocoll, and 1,321,979 consisted of ADSs to be sold by certain identified shareholders. The total public offering price was approximately $29.9 million, of which Innocoll received approximately $16.9 million, certain Innocoll shareholders received approximately $7.2 million, and certain Innocoll employees received $4.3 million. The capital raise was plainly insufficient to Innocoll's needs. In fact, as Innocoll admitted on its conference call to discuss its Q2 2014 earnings (the "Q2 2014 Earnings Call"), taking place on August 14, 2015, the capital raise was only sufficient to fund its operations through the first half of 2016, though Innocoll projected it would file XaraColl's NDA in the second half of 2016. Defendant Zook signed the April 2015 Registration Statement.

109. The April 2015 Registration Statement was declared effective on April 23, 2015.

110. The April 2015 Registration Statement provided, in relevant part:

> XaraColl has been studied in one Phase 1 and four completed Phase 2 clinical trials enrolling approximately 184 patients, including 103 patients in two Phase 2 trials in hernia repair at doses of 100 mg and 200 mg of bupivacaine. Results from both trials demonstrated that XaraColl reduces both pain intensity and opioid consumption with the 200 mg dose resulting in an overall greater combined effect at 48 hours. XaraColl-treated patients in the 100 mg dose trial experienced significantly less pain through 24 hours, 48 hours and 72 hours. In our subsequent 200 mg dose trial, XaraColl demonstrated a statistically significant reduction in

> opioid consumption through 24 and 48 hours, and demonstrated a statistical trend in reduction in pain intensity through 24 hours. When we apply the Silverman method, a validated statistical analysis that integrates the patient's pain intensity with opioid consumption, to these results, the 100 mg dose trial demonstrated a statistically significant reduction at 24 hours and the 200 mg dose trial demonstrated a statistically significant reduction at both 24 and 48 hours as well as a statistical trend through 72 hours. These results are indicative of a clear dose-related response. The primary endpoint in our two planned Phase 3 trials will use this integrated Silverman method assessment of pain and opioid consumption, ***as agreed to with the FDA in our end-of-Phase 2 meeting***.

111. The April 2015 Registration Statement also provided:

> The primary endpoint in our two planned Phase 3 trials will use this integrated Silverman method assessment of pain and opioid consumption, ***as agreed to with the FDA in our end-of-Phase 2 meeting.***

112. The April 2015 Registration Statement also provided:

> Thus, we believe that by applying the Silverman method and integrating both pain intensity and opioid consumption into a single endpoint rather than assessing a single parameter alone, we can generate a more meaningful interpretation of trial results. ***Following our end-of-Phase 2 meeting, the FDA agreed to permit us to pursue such integrated end point in our Phase 3 trial.***

113. The emphasized statements were misleading because there was a substantial risk that the FDA would find that XaraColl is a drug-delivery combination product, thus requiring additional tests for approval, including a pharmacokinetic clinical study and other non-clinical studies. The purpose of FDA meetings is for the sponsor to raise, discuss and resolve any issues that could lead to denial of approval. Therefore, by stating that Innocoll had held a XaraColl Post Phase 2 meeting with the FDA, and that the FDA had agreed to a plan for XaraColl, Defendants conveyed that it had resolved all issues in the design of clinical trials they were aware of that could lead to denial of approval. In fact, Innocoll and its officers knew that XaraColl had device components which there was a substantial risk would require separate approval from the FDA following separate clinical trials and other studies. Yet as Defendants admitted to an analyst following the end of the Class Period, Defendants never discussed what trials and/or studies

would be required for approval of XaraColl's device components with the FDA. *See* ¶151, below. Therefore, Defendants' statements gave the misleading impression that the FDA had deemed that all that was required for approval was for XaraColl to meet its Phase 3 clinical trial endpoints, when in fact, there was a substantial risk that the FDA would not file or approve XaraColl's NDA because it would require Innocoll to show that XaraColl's device components were safe and effective through additional studies.

114. On October 8, 2015, Innocoll filed an Amended Registration Statement on Form F-3/A (the "October 2015 Shelf Registration Statement"). Form F-3 registration statements are called shelf registration statements because they permit SEC-registered companies to register shares and place them "on the shelf" to be sold at a later time. But SEC rules provide that any future reports on Form 20-F, as well as any prospectuses, are incorporated into any Form F-3 that is declared effective. The October 2015 Shelf Registration Statement was declared effective on October 9, 2015.

115. On March 17, 2016, Innocoll filed its 20-F for the year ended December 31, 2015 (the "2015 20-F"), which was signed by Defendant Zook.

116. The 2015 20-F provided:

> After the revised guidance we received from the FDA in July 2015, we determined that we will rely upon a primary endpoint of summed pain intensity, or SPI, in our two Phase 3 trials. Based on the results of our pivotal pharmacokinetic study in which we tested both a 200 mg and a 300 mg dose compared to standard bupivacaine infiltration, are running both Phase 3 trials in parallel, focusing only on the 300 mg dose. ***The FDA deemed our single-dose approach acceptable in our recent Type C meeting*** [in July 2015]. Because bupivacaine is believed to work locally by blocking the generation and the conduction of nerve impulses and it is considered dose dependent, we believe a higher dose should increase the local analgesic effect. In September 2015, the first patient was dosed in both our MATRIX-1 [] and MATRIX-2 Phase 3 studies for the treatment of postoperative pain following open hernia repair with mesh using XaraColl, Innocoll's surgically implantable and bioresorbable bupivacaine-collagen matrix. Our MATRIX Phase 3 studies are two identical randomized,

placebo-controlled, double-blinded studies to investigate the safety and efficacy of XaraColl, with pivotal data anticipated in the first half of 2016. ***We expect to submit an NDA for XaraColl at the beginning of the fourth quarter of 2016.***

117. The 2015 20-F continued:

The FDA has reviewed the data from [XaraColl's Phase 2] ***study and agreed*** with with [sic] Innocoll's decision to proceed with the evaluation of the single 300mg dose of XaraColl in the current Phase 3 program.

118. The 2015 20-F added:

The FDA has approved [XaraColl's Phase 3 study] protocol and we commenced testing XaraColl at the 300 mg dose in the third quarter of 2015, with pivotal data anticipated in the first half of 2016. We previously received topline data from our pivotal pharmacokinetic study in which we tested both a 200 mg and a 300 mg dose versus standard bupivacaine infiltration which supports the selection of a 300 mg dose of XaraColl to be tested in our MATRIX Phase 3 efficacy trials. We had initially planned to conduct our Phase 3 trials using a single, integrated endpoint, validated in pain studies, that integrates and weights the patient's pain score and use of rescue analgesia equally, known as the Silverman method so that the results can take into account a patient's choice to suffer more pain or take higher dosages of rescue analgesia. However, ***in accordance with recommendations that we received from the FDA in connection with our recent Type C meeting*** [in July 2015], we are not using an integrated endpoint in our Phase 3 trials and instead rely upon a primary endpoint of SPIDfor [sic] both trials.

We also increased the number of patients from 240 to 300 to ensure that the safety database from our studies will include no less than 500 subjects, ***as requested by the FDA.***

119. The emphasized statements were misleading because there was a substantial risk that the FDA would find that XaraColl is a drug-delivery combination product, thus requiring additional tests for approval, including a pharmacokinetic clinical study and other non-clinical studies. The purpose of FDA meetings is for the sponsor to raise, discuss and resolve any issues that could lead to denial of approval. Therefore, by stating that Innocoll had held the XaraColl

Post Phase 2 and the July 2015 meeting with the FDA, and that the FDA had agreed to a plan for XaraColl, Defendants conveyed that it had resolved all issues in the design of clinical trials they were aware of that could lead to denial of approval. In fact, Innocoll and its officers knew that XaraColl had device components which there was a substantial risk would require separate approval from the FDA following separate clinical trials and other studies. Yet as Defendants admitted to an analyst following the end of the Class Period, Defendants never discussed what trials and/or studies would be required for approval of XaraColl's device components with the FDA. *See* ¶151, below. Therefore, Defendants' statements gave the misleading impression that the FDA had deemed that all that was required for approval was for XaraColl to meet its Phase 3 clinical trial endpoints, when in fact, there was a substantial risk that the FDA would not file or approve XaraColl's NDA because it would require Innocoll to show that XaraColl's device components were safe and effective through additional studies.

120. Also on March 17, 2016, Innocoll held a conference call to discuss its Q4 2015 results (the "Q4 2015 Earnings Call"). On the call, an analyst specifically asked whether there was anything that Innocoll needed to do other than the Phase 3 studies to obtain approval for XaraColl:

> <Analyst> Okay, great. And are there any other nonclinical things that you have to get out of the way for the XaraColl filing and safety database, any kind of manufacturing issues that you need to address, like anything else that is nonclinical related to XaraColl will have to be prepared before you file?
> <Defendant Zook> ***Nothing that hasn't already been done and shared with the FDA*** so we are good to go once we get the results with these two preclinical programs before we get the green light.

121. Defendant Zook's statement was false because Innocoll had not completed the tests necessary to approve XaraColl's device components nor obtained the FDA's assurance that such tests were unnecessary. Defendant Zook's statement thus concealed the substantial risk that

XaraColl would not be approved because Innocoll failed to provide evidence necessary for the approval of XaraColl's device component.

122. On May 16, 2016, Innocoll filed a post-effective amendment to the Registration Statement (the "Amendment").

123. Defendant Zook signed the Amendment.

124. The Amendment provided:

> After the revised guidance we received from the FDA in July 2015, we determined that we will rely upon a primary endpoint of summed pain intensity, or SPI, in our two Phase 3 trials. Based on the results of our pivotal pharmacokinetic study in which we tested both a 200 mg and a 300 mg dose compared to standard bupivacaine infiltration, are running both Phase 3 trials in parallel, focusing only on the 300 mg dose. ***The FDA deemed our single-dose approach acceptable in our recent Type C meeting*** [in July 2015]. Because bupivacaine is believed to work locally by blocking the generation and the conduction of nerve impulses and it is considered dose dependent, we believe a higher dose should increase the local analgesic effect. In September 2015, the first patient was dosed in both our MATRIX-1 [] and MATRIX-2 Phase 3 studies for the treatment of postoperative pain following open hernia repair with mesh using XaraColl, Innocoll's surgically implantable and bioresorbable bupivacaine-collagen matrix. Our MATRIX Phase 3 studies are two identical randomized, placebo-controlled, double-blinded studies to investigate the safety and efficacy of XaraColl, with pivotal data anticipated in the first half of 2016. ***We expect to submit an NDA for XaraColl at the beginning of the fourth quarter of 2016.***

125. The emphasized statements were misleading because Defendants knew or were reckless in not knowing that there was a substantial risk that the FDA would find that XaraColl is a drug-delivery combination product, thus requiring additional tests for approval, including a pharmacokinetic clinical study and other non-clinical studies. The purpose of FDA meetings is for the sponsor to raise, discuss and resolve any issues that could lead to denial of approval. Therefore, by stating that Innocoll had held the XaraColl Post Phase 2 and the July 2015 meeting with the FDA, and that the FDA had agreed to a plan for XaraColl, Defendants conveyed that it had resolved all issues in the design of clinical trials they were aware of that could lead to denial

of approval. In fact, Innocoll and its officers knew that XaraColl had device components which there was a substantial risk would require separate approval from the FDA following separate clinical trials and other studies. Yet as Defendants admitted to an analyst following the end of the Class Period, Defendants never discussed what trials and/or studies would be required for approval of XaraColl's device components with the FDA. *See* ¶151, below. Therefore, Defendants' statements gave the misleading impression that the FDA had deemed that all that was required for approval was for XaraColl to meet its Phase 3 clinical trial endpoints, when in fact, there was a substantial risk that the FDA would not file or approve XaraColl's NDA because it would require Innocoll to show that XaraColl's device components were safe and effective through additional studies.

126. On May 25, 2016, Innocoll published a press release announcing the results of its XaraColl Phase 3 trials. The press release stated that the Phase 3 "Data supports on-schedule NDA filing this year."

127. That same day, Innocoll held a conference call to discuss the XaraColl Phase 3 trial results. On the call, analysts repeatedly asked whether there were any remaining steps necessary for filing the NDA; Defendants Zook and Russell both denied that there were any:

> <Analyst>: Thanks. I had a couple [of questions]. First, ***can you just remind us if there are any other gating factors beyond the clinical trial to the NDA filing***, and the manufacturing hurdles, if any, that we'd need to be aware of? […]
>
> <Defendant Zook> Thanks. What I will do at this point, David, I'll ask Nigel [Jones] to weigh a little bit on your third question, on the feedback we've received anecdotally, because he's had the most interactions with people involved with the trials, so he can give you some sense of how they see the product, and then what other potential applications there might be.
>
> ***As far as any other gate staging moment, we believe now that we're in a good position to move forward with our NDA submission, and as we had indicated, we want to get that done this year***. As you also know, we have been investing in our manufacturing processes, because we wanted to be able to scale up in a very

> cost-efficient way to meet our commercial requirements. Those plans are right on track, and will mirror up, and coincide with the NDA submission. ***We don't see anything beyond those two other points*** unless I've missed something, in which case I'll ask Nigel [Jones] or Lesley [Russell] to weigh in. Then, I'll turn it to Nigel [Jones] on the other question.
>
> […]
>
> <Analyst> Terrific, and I really appreciate the time. Just one last question with regard to the ability to submit the data from an NDA perspective, what's the key issue in terms of gating factor that would determine the timing for the NDA submission? Is it [INAUDIBLE], the analysis of the data, the CMC reviews What do you see as the most critical piece on that path, now, going forward?
>
> <Defendant Russell> ***I don't think there really are any gating factors.*** Obviously, we now need to write up all of the sections of the NDA with all the new clinical data, and the integrated summaries, and overall summaries. Obviously CMC components are a large part of an NDA. That's also on track. We feel pretty good about filing the NDA at the end of the third quarter, beginning of the fourth quarter, around that time frame. We feel that everything is on track to be able to do that.

128. Defendants Zook and Russell's statements were false because there was at least one additional gating factor – namely, that Innocoll had not conducted the tests necessary for XaraColl's approval nor obtained the FDA's assurances that the tests were unnecessary. Defendants Zook and Russell's statements thus concealed a substantial risk that XaraColl would not be approved because Innocoll failed to provide evidence necessary for the approval of XaraColl's device component.

129. The announcement that XaraColl was all but ready for an NDA filing immediately sent Innocoll's stock price soaring from its previous close of $7.11/share to close at $10.51/share on May 25.

130. On June 13, 2016, filed a Preliminary Prospectus Supplement (the "June 2016 Preliminary Prospectus") to the F-3 Registration Statement, which provided:

> After the revised guidance we received from the FDA in July 2015, we determined that we will rely upon a primary endpoint of summed pain intensity, or SPI, in our two Phase 3 trials. Based on the results of our pivotal pharmacokinetic study in which we tested both a 200 mg and a 300 mg dose compared to standard bupivacaine infiltration, we ran both Phase 3 trials in parallel, which focused only on the 300 mg dose. ***The FDA deemed our single-dose approach acceptable in our recent Type C meeting.*** Because bupivacaine is believed to work locally by blocking the generation and the conduction of nerve impulses and it is considered dose dependent, we believe a higher dose should increase the local analgesic effect. In September 2015, the first patient was dosed in both our MATRIX-1 [] and MATRIX-2 Phase 3 studies for the treatment of postoperative pain following open hernia repair with mesh using XaraColl, Innocoll's surgically implantable and bioresorbable bupivacaine-collagen matrix. ***Our MATRIX Phase 3 studies are two identical randomized, placebo-controlled, double-blinded studies to investigate the safety and efficacy of XaraColl, with pivotal data anticipated in the first half of 2016. We expect to submit an NDA for XaraColl in the second half of 2016.***

131. The June 2016 Preliminary Prospectus further provided:

> We also initiated our Phase 3 trials for XaraColl in the third quarter of 2015, and announced top-line pivotal data in May 2016 that each study had achieved its primary endpoint as a post-operative pain relief treatment immediately following open abdominal hernia repair. ***These two pivotal Phase 3 clinical trials will form the basis of the evidence for efficacy for the NDA for XaraColl, which we expect to submit prior to the end of 2016.***

132. The June 2016 Preliminary Prospectus further provided:

> Develop XaraColl for treatment of post-operative pain. Based on the topline data received from our pivotal pharmacokinetic study in which we tested both a 200 mg and a 300 mg dose versus standard bupivacaine infiltration, we conducted both our Phase 3 efficacy studies with a 300 mg dose of XaraColl. ***The FDA agreed with our single-dose approach.*** We initiated our two Phase 3 efficacy studies in the third quarter of 2015. We anticipate pivotal data from these trials in the first half of 2016.

133. The June 2016 Preliminary Prospectus further provided:

> We intend to use the net proceeds from this offering primarily to fund costs associated with our pre-commercialization activities relating to XaraColl, including through the filing ***and anticipated approval of its NDA[.]***

134. The emphasized statements were misleading because there was a substantial risk that the FDA would find that XaraColl is a drug-delivery combination product, thus requiring

additional tests for approval, including a pharmacokinetic clinical study and other non-clinical studies. The purpose of FDA meetings is for the sponsor to raise, discuss and resolve any issues that could lead to denial of approval. Therefore, by stating that Innocoll had held the XaraColl July 2015 meeting with the FDA, and that the FDA had agreed to a plan for XaraColl, Defendants conveyed that it had resolved all issues in the design of clinical trials they were aware of that could lead to denial of approval. In fact, Innocoll and its officers knew that XaraColl had device components which there was a substantial risk would require separate approval from the FDA following separate clinical trials and other studies. Yet as Defendants admitted to an analyst following the end of the Class Period, Defendants never discussed what trials and/or studies would be required for approval of XaraColl's device components with the FDA. *See* ¶151, below. Therefore, Defendants' statements gave the misleading impression that the FDA had deemed that all that was required for approval was for XaraColl to meet its Phase 3 clinical trial endpoints, when in fact, there was a substantial risk that the FDA would not file or approve XaraColl's NDA because it would require Innocoll to show that XaraColl's device components were safe and effective through additional studies.

135. The filing of the Prospectus Supplement caused Innocoll's stock price to fall from $10.95/share to $8.85/share on June 14, 2016.

136. Just days later, on June 17, Innocoll filed a final Prospectus Supplement (the "June 2016 Final Prospectus"), which made identical false statements.

137. On August 17, 2016, Defendants held a conference call to discuss Innocoll's results for the third quarter of 2016 (the "Q3 2016 Earnings Call"). On the call, in prepared remarks, Defendant Zook acknowledged that the collagen sponge was an essential part of XaraColl:

> Finally, we're excited that the positive outcome [of XaraColl's Phase 3 clinical trials] also provided validation for our collagen-matrix as a unique delivery platform. We believe this indicates tremendous promise for other pipeline products and we continue to expect to deliver topline Phase 3 results for one of those products, Cogenzia in the early part of the fourth quarter.

138. On November 3, 2016, Innocoll issued a press release announcing that (a) Cogenzia had failed Phase 3 trials and (b) as a result, Innocoll was abandoning Cogenzia. In the same press release, Innocoll also announced (c) that it was submitting an NDA for XaraColl:

> Innocoll Announces Top-Line Data From Phase 3 Trials With COGENZIA and NDA Submission for XARACOLL
>
> * * *
>
> ***Innocoll also announced the submission of a New Drug Application (NDA) for XARACOLL (bupivacaine HCl collagen-matrix implants) to the U.S. Food and Drug Administration (FDA) for the treatment of postsurgical pain.*** The submission was based upon the successful results of the MATRIX trials which showed statistically significant differences in the primary endpoint, the sum of pain intensity in both studies, as well as statistically significant reductions in opioid use and other secondary endpoints.

139. On November 4, 2016, Innocoll also held a conference to discuss both the COGENZIA results and XaraColl submission.

140. On the call, in pre-prepared responses to questions that had been posed earlier, Defendants all but guaranteed that the FDA would approve XaraColl:

> <Defendant Zook>: Great. Thanks. Again, we'll open up the line for other questions relative to Cogenzia in just a moment. XaraColl, we did announce, of course, our excitement about getting the XaraColl NDA submission in, so people did ask kind of baseline your confidence in the overall NDA submission and what's the starting point? What is it that we are pursuing as our label?
> <Defendant Russell>: I think I've been pretty vocal about how confident I am that XaraColl will get approved. I mean this a product that has had two very successful Phase 3 studies achieving the primary endpoint with high degree of statistical significance and really no safety issues at all. And, in fact, actually one could argue potential safety benefit and the fact that we also see a reduction in the opioid-related adverse events. ***So, this should lead to a pretty straightforward approval.***

> I think people always ask then, what is the label, what will the label actually show. And that's a bit that will require some negotiation, but we have you know filed for the broadest claim of postsurgical analgesia. We have requested inclusion with 48 time points in the label both individual studies and the pooled analysis. And we've also asked some language recognizing that the use of XaraColl has reduced the influence of opioid-related adverse events. And so – and I think if we get any one of those, that's a really significant outcome for us. ***And as I've said, approval, I think, is not in question.*** It's exactly what the label may show at the end of the day.

141. The emphasized statements misleadingly conveyed to investors that Innocoll had raised and satisfied all potential gating issues with the FDA at its pre-NDA and July 2015 meetings, and that the FDA had approved of Innocoll's plan to submit only Phase 3 trials, omitting any trials for the device portion of the XaraColl application. In fact, not only had Innocoll not satisfied the device gating issue, it had not even raised the issue with the FDA. The emphasized statements thus concealed a substantial risk that XaraColl would not be approved because Innocoll failed to provide evidence necessary for the approval of XaraColl's device component.

142. On November 22, 2016, Innocoll filed a press release with the SEC announcing Innocoll's financial and operating results for the third quarter of 2016 and providing corporate updates, stating in relevant part:

> ***"As we recently announced, Innocoll achieved an exciting, new milestone with the submission of a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA), for XARACOLL for the treatment of post-surgical pain,"*** said [Defendant] Zook, Chief Executive Officer of Innocoll. ***"We anticipate an FDA acceptance of the NDA, for review, by the end of this year, and with a target Prescription Drug User Fee Act (PDUFA) action date in late August 2017, this achievement will take us another step closer to the approval and launch of XARACOLL in potentially less than one year.*** [...] ***We plan to manage our cash runway until after the anticipated XARACOLL NDA approval, expected in the third quarter of 2017, and we feel confident about our ability to finance the commercialization of XARCOLL as well as our pipeline".***
>
> Third Quarter 2016 and Recent Highlights

- Submitted an NDA for XARACOLL to the FDA for the treatment of postsurgical pain
  - ***FDA acceptance anticipated by the end of 2016, with a target PDUFA action date in late August 2017.***

143. The emphasized statements misleadingly conveyed to investors that Innocoll had raised and satisfied all potential gating issues with the FDA at its pre-NDA and July 2015 meetings, and that the FDA had approved of Innocoll's plan to submit only Phase 3 trials, omitting any trials for the device portion of the XaraColl application. In fact, Innocoll had not raised the device issue with the FDA at all. Nor had it been satisfied. The emphasized statements thus concealed a substantial risk that XaraColl would not be approved because Innocoll failed to provide evidence necessary for the approval of XaraColl's device component.

144. On November 22, 2016, the Company also held a conference call to discuss its third quarter of 2016 filings (the "Q3 2016 Earnings Call"). On the Q3 2016 Earnings Call, Defendant Zook represented that approval was guaranteed:

> First, we were very pleased to announce recently the achievement of an exciting new milestone for Innocoll. ***We submitted our first new drug application to the U.S. Food and Drug Administration in October for XaraColl for the treatment of post-surgical pain. We expect to hear back from the FDA by the end of this year with respect to their acceptance of the NDA filing. This would target a PDUFA action date in late August putting us on track to the approval and commercialization of a branded therapeutic in potentially less than a year.***
>
> * * *
>
> As you can see, XARACOLL posted positive Phase 3 data back in the second quarter and we submitted an NDA for post-surgical analgesia last month. ***This is a 505(b)(2) application with a standard 10-month review and thus we anticipate being able to commercialize the product soon after an approval in Q3 of 2017.***

145. On the same conference call, Defendant Russell spoke about XaraColl's NDA, stating in relevant part:

> So, the XaraColl program, as [Defendant Zook] mentioned, we did submit our NDA based on our Phase 3 trial results and I'll give you some key specifics on what we asked for with respect to the potential label.
>
> We submitted for a broad indication for single dose placement into the surgical site to produce post-surgical analgesia. We did include results of both the MATRIX-1 and MATRIX-2 trials and the pool data for the demonstration of post-surgical analgesic effect of 48 hours.
>
> We also included language related to XaraColl's statistically significant reduction in total opioid consumption and increase in median time to first opioid use as well as the reduction in the incidences of opioid related adverse event.
>
> ***We're quite confident in our CMC package and we are well-prepared for the upcoming NDA preapproval inspection.*** We continue to plan for medical publication and presentation of the full analysis of XaraColl's Phase 3 data, which are targeted for the second quarter of 2017.

146. The emphasized statements misleadingly conveyed to investors that Innocoll had raised and satisfied all potential gating issues with the FDA at its pre-NDA and July 2015 meetings, and that the FDA had approved of Innocoll's plan to submit only Phase 3 trials, omitting any trials for the device portion of the XaraColl application. In fact, Innocoll had not raised the device issue with the FDA at all. Nor had it been satisfied. The emphasized statements thus concealed a substantial risk that XaraColl would not be approved because Innocoll failed to provide evidence necessary for the approval of XaraColl's device component.

147. In prepared remarks, Defendant Zook acknowledged that the collagen sponge itself was important to XaraColl's use and functioning, stating that "[s]urgeons may have concerns about the implants and the matrix may be difficult to use."

148. But Defendant Zook also emphasized that the collagen sponge was the basis of XaraColl's appeal:

> <Defendant Zook>: Yeah, <analyst name>, I think the reason, it's interesting right, for the last few years we've been spending the bulk of our time with the

investor community and these were primarily the questions that seem to come up and not surprisingly they've been kind of talking points from almost a counter-detailing effort about the technology and most people just don't have access to the technology.

So for example if you have the impression and you ask an open ended question to a doctor, would you ever want to use a sponge or leave a sponge in someone, of course, the answer is no to that. ***But when the doctors actually see and feel the technology, understand that it's a collagen matrix that collapses upon itself, they have absolutely no apprehension whatsoever about using the product.***

Likewise, when you start to show them where and how the product is used as part of a surgical technique, they find it actually part of the normal surgical procedures. They are inserting meshes all the time; for them to use an implantable as part of the surgical procedure was unsolicited, something that was quite simple and easy to use and avoids the need for user knowledge on injection side and avoids the risk of intravascular injection.

And so these came up as just kind of natural talking points around the technology itself. We ask questions, we weren't as specific as, do you have concerns about using this, but I think in broad ways it came across in the in-depth interview. So we feel quite confident with the feedback we were getting.

VI. DEFENDANTS' FALSE STATEMENTS CAUSED CLASS MEMBERS' LOSSES

149. On December 29, 2016, after close of trading, Innocoll issued a press release stating that it had received a Refusal to File letter from the FDA for XaraColl. The press release stated in relevant part:

> Innocoll Receives Refusal to File Letter from U.S. FDA for XARACOLL® (bupivacaine HCl collagen-matrix implants) New Drug Application
>
> ATHLONE, Ireland, Dec. 29, 2016 (GLOBE NEWSWIRE) -- Innocoll (NASDAQ:INNL), a global, commercial-stage, specialty pharmaceutical company, today announced that ***it has received a Refusal to File letter from the United States Food and Drug Administration (FDA) for XARACOLL, the company's product candidate for the treatment of postsurgical pain.***
>
> Upon preliminary review, ***the FDA determined that the application, which was submitted in October 2016, was not sufficiently complete to permit a substantive review. In the Refusal to File letter, the FDA indicated among other things, that XARACOLL should be characterized as a drug/device combination, which would require that the Company submit additional information.*** The company will request a Type A meeting with the FDA to respond to several issues believed to be addressable and seek clarification of what additional information, if any, will be required. Additional details will be disclosed in the future after discussions with the FDA.

> "We expect to work with the FDA over the coming weeks in an effort to address the open issues and to define a path forward for a successful re-filing of our application at the earliest point in time," said [Defendant] Zook, CEO of Innocoll.

150. On December 30, 2016, Innocoll's share price fell $1.08/share from its previous close to close at $0.69/share, down over 61%, damaging investors.

151. On December 29, 2016, an analyst employed by JMP Securities published a report providing, in relevant part, that Innocoll's "[m]anagement commented to us that the FDA did not raise the drug/device issue at the pre-NDA meeting." Far from an excuse, this is in fact a grave admission. As further set out above, the purpose of a meeting with the FDA is to answer the company's questions. Since Innocoll knew that there was a drug/device issue, it was Innocoll's responsibility to raise the issue at the FDA meetings, rather than hoping the FDA's inattention would allow it to obtain approval for XaraColl without conducting the device studies.

152. On March 29, 2017, Innocoll admitted that the FDA would require that Innocoll conduct "an additional short-term pharmacokinetic study and several short-term non-clinical toxicology and biocompatibility studies [as well as] additional manufacturing information." Innocoll further announced that these studies would not be completed until the end of 2017. Innocoll filed the new NDA no earlier than February 12, 2018.

VII. DEFENDANTS HAD MOTIVES TO MAKE FALSE STATEMENTS

A. Innocoll Would Have Ceased To Exist If Defendants Had Not Falsely Boosted Xaracoll's Prospects

153. As a development-stage company with *de minimis* revenues, Innocoll depends on financing transactions for the cash it needs to complete its FDA trials and obtain approval for its products, XaraColl and Cogenzia.

154. Innocoll consumes cash ferociously. Innocoll's XaraColl and Cogenzia Phase III trials are extremely expensive. In its Q1 2015 earnings call, Zook estimated that Innocoll's Phase III trials would cost $50 million, and that it had only spent $10 million of that $50 million. Indeed, between March 31, 2014 and December 31, 2016, Innocoll spent approximately $100 million more than it earned.

155. Innocoll's 2015 20-F reported that Innocoll's "ability to continue as a going concern is dependent on [its] ability to raise additional financ[ing] by way of debt and/or equity offerings to enable us to fund our clinical trial programs."

156. Innocoll's capital needs would not end with FDA approval of either of its products. To commercialize XaraColl, Innocoll must, among other things, hire a large sales force. Indeed, a Piper Jaffray analyst noted in a November 22, 2016 report that it anticipated that Innocoll would have to conduct another offering to fund the U.S. commercialization of XaraColl.

157. Innocoll could only obtain debt financing at very high rates. For example, Innocoll's debt facility, entered into on March 27, 2015, bore interest at 12% per year, compounded annually. Even if Innocoll could take out more debt to finance its operations, the debt would be riskier for the lender and thus would bear higher interest rates.

158. Innocoll thus had to meet its financing needs by selling its shares.

159. Innocoll aimed to generate enough cash from its offerings to fully fund its operations, but could never do so, as it admitted in each offering:

a. On the Q3 2014 Earnings Call, Innocoll admitted that the amount raised in its IPO was "lower than [Innocoll's] initial target."

b. Innocoll's next capital raise took place in April 2015. As Innocoll admitted in the Q2 2015 Earnings Call, the April 2015 capital raise

> was only sufficient to fund its operations through the first half of 2016, though Innocoll projected it would file XaraColl's NDA in the second half of 2016. And indeed, just five months later, Innocoll filed a registration statement to register $150 million in Innocoll shares for future resale.

160. The limited interest in Innocoll's shares left it tethered to capital markets. It had to issue relentless good news showing that approval of its devices was impending.

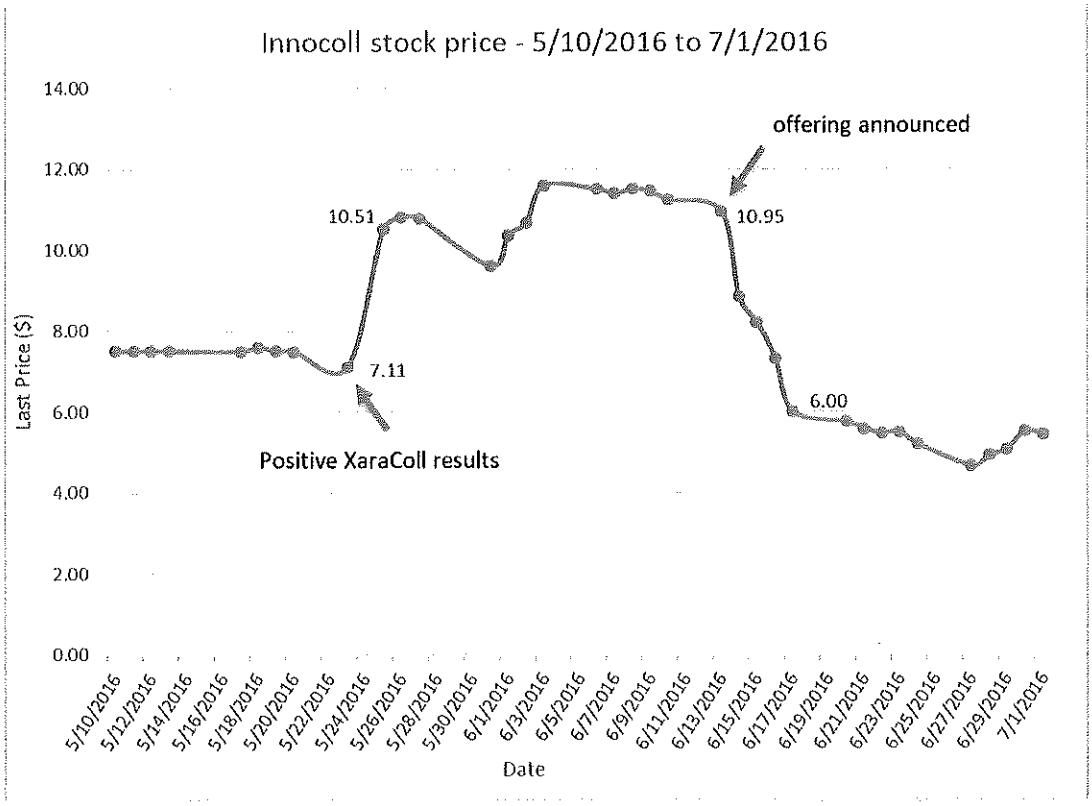
161. XaraColl's purportedly imminent FDA approval was the best arrow in Innocoll's quiver. When Innocoll announced positive results from XaraColl's Phase 3 trials on May 25, 2016, its stock price shot up from $7.11 to $10.51, or an increase of 47.8%.

162. Buoyed by the price increase, weeks later on June 13, Innocoll filed the June 2016 Preliminary Prospectus to sell $50.0 million of its shares, and for selling shareholders to sell $15.0 million, of Innocoll shares, for a total of $65.0 million.

163. The day after the raise was announced, Innocoll's stock price fell by 19.1%.

164. Innocoll and the selling shareholders were forced to drastically cut the offering size. On June 17, 2016, Innocoll reduced the amount being offered to $40.0 million, or almost 40% less.

165. By the time the offering was conducted on June 20, 2016, Innocoll's stock price had fallen to $6.00/share, down 45% from the time of the announcement.



166. Innocoll conducted its financing operations on the razor's edge. Even with a promise that XaraColl would be approved, and soon, Innocoll could not sell the shares it sought to and its attempt caused its stock price to collapse. It was thus critical to Innocoll's financing operations that Defendants artificially inflate Innocoll's stock price by misleadingly overstating XaraColl's chance of approval.

B. Innocoll Overstated XaraColl's Prospects To Entice A Suitor Or Licensee

167. Since at least March 2016, Defendants have been seeking to monetize XaraColl, either by selling Innocoll outright to an acquirer or by licensing or selling the rights to XaraColl.

168. On March 3, 2016, Defendant Zook and Innocoll's CFO met with Gurnet Point, a venture capital and buyout firm, to discuss an equity or debt investment by Gurnet Point in Innocoll.

169. Shortly after Innocoll announced positive Phase 3 results for XaraColl, Zook, Gurnet Point, and the Chair of Innocoll's Board met repeatedly to discuss Gurnet Point's interest in making an investment in Innocoll.

170. Then, on June 12, 2016, Gurnet Point called Zook and told him Gurnet Point declined to acquire a controlling stake in Innocoll. It was only one day later that Innocoll filed the prospectus for the June 2016 Offering.

171. While Gurnet Point initially declined to make a major investment in Innocoll, on July 13, 2016, it requested that Innocoll prepare a management presentation with a view to Gurnet Point's making an offer to acquire Innocoll. Zook, Innocoll's CFO, and its Chief Commercial Officer, its three highest-paid officers who all worked out of Philadelphia, delivered the presentation in person at Gurnet Point's Cambridge Massachusetts office ***the very next day***.

172. In August 2016, Zook hired (a) Piper Jaffray to advise it on the potential acquisition, and (b) Deloitte Corporate Finance LLC to advise it on potential deal structures and strategic partners. On August 31, 2016, Zook and Innocoll's CFO made a presentation to Innocoll's Board concerning Innocoll's potential acquisition, while Piper Jaffray made a presentation concerning Innocoll's valuation.

173. On September 21, 2016, Gurnet Point delivered a preliminary non-binding offer to acquire Innocoll for $9.50/share in cash. The offer was based entirely on Gurnet Point's valuation of XaraColl, as Gurnet Point correctly perceived that Cogenzia had no value. That Gurnet Point's offer was based entirely on XaraColl's value gave Defendants even more of an incentive to overstate its chances of FDA approval.

174. At that time, the analysts covering Innocoll had price targets of $23.00/share (JMP), $18.00/share (Janney), and $15.00/share (Piper Jaffray), and Innocoll's shares had traded

for as much as $12.94 a mere three months earlier. Zook is one of seven directors on Innocoll's Board.

175. Accordingly, on September 23, 2016, Innocoll's Board rejected the offer, and Zook communicated the rejection to Gurnet Point.

176. Before September 23, 2016, Gurnet Point had dealt almost entirely with Zook. Yet on September 23, the Chair of Innocoll's Board separately emailed Gurnet Point to state that the Board was not prepared to accept Gurnet Point's offer. And on September 26, the Chair of Innocoll's Board spoke directly with Gurnet Point to discuss the Board's rationale. Defendant Zook was not on the line.

177. Gurnet Point continued to discuss acquiring Innocoll even after Innocoll's Board rejected its offer. But thereafter, Gurnet Point negotiated principally with the Chair of Innocoll's Board and obtained information from executive officers other than Zook, even though Zook and Gurnet Point are in the same time zone while the Chair of Innocoll's Board resides in London.

178. Innocoll also sought to monetize XaraColl by licensing or selling the intellectual property rights.

179. In April 2016, Innocoll hired Locust Walk Partners LLC to lead a joint effort with representatives of Innocoll to identify and contact pharmaceutical companies that might be interested in licensing or acquiring XaraColl's European rights. On September 23, 2016, Innocoll expanded the search to find a buyer for XaraColl's U.S. rights, too. Altogether, between April and October 2016, Innocoll approached about 50 potential buyers.

180. Defendants misled investors about the likelihood that XaraColl would be approved by the FDA because they were seeking to monetize it.

C. Zook Made Bold Promises That He Was Not Keeping

181. On his inaugural call as Innocoll's CEO taking place on March 19, 2015, Zook acknowledged that Innocoll had tarried in pursuing its products through to FDA approval. Under his leadership, though, Zook boasted that Innocoll now had both the means and the will to carry its projects through to approval: "[T]he historical lack of financial resources that led to delays in the delivery of programs is behind us. And we plan to focus on achieving all our clinical milestones." Zook added that "meeting our key delivery dates is our highest priority."

182. Thus, with both the means and the will, Zook claimed that Innocoll would reach four targets within 12 months, before March 2016. The very first target on Innocoll's list was to complete both XaraColl and Cogenzia's clinical trials. Zook highlighted this target in particular, stating that "[w]e need to advance our late-stage portfolio [of XaraColl and Cogenzia] on time and on budget." Zook specified that the budget was $50 million, including what had already been spent.

183. Finally, Zook claimed that Innocoll had enough cash to take XaraColl and Cogenzia through their trials, and would only need additional cash to support the regulatory process and commercialization.

184. Innocoll did not meet any of Zook's targets.

185. Innocoll did not complete clinical trials for XaraColl until May 2016, and did not complete clinical trials for Cogenzia until October 2016.

186. Nor did Innocoll come close to meeting its budget. Having already spent $4.3 million in 2014, Innocoll's research & development costs soared to $29.8 million in 2015 and $38.7 million in 2016 – or more than $20 million over budget.

187. And Innocoll was forced into repeated dilutive offerings in order to fund the increased expenditures – the April 2015 $29.9 million offering and the June 2016 $40.1 million offering.

188. Zook thus faced pressure to cut whatever corners were necessary to live up to his own bold promises.

D. Given the State of Her Career, Defendant Russell Faced Pressure Not To Insist That Innocoll Conduct Additional Trials For XaraColl

189. Russell joined Innocoll in April 2016. Prior to joining Innocoll, Russell served as Chief Operating Officer and Chief Medical Officer of TetraLogic Pharmaceuticals Corp. from August 2013 through March 2016.

190. TetraLogic was an ignominious disaster.

191. TetraLogic's December 2013 IPO raised $57 million selling shares at $7.00/share, with a total market capitalization at its IPO of $148 million. Its stock price quickly reached a high of $12.25/shares.

192. TetraLogic collapsed in less than two years. On May 6, 2015, TetraLogic announced that it had halted its trial of its principal drug, Birinapant. Its stock price fell to $2.40/share, for a total market capitalization of $56 million.

193. Then, on January 6, 2016, TetraLogic announced that it was terminating its trials of Birinapant, as it failed to show effectiveness. Its stock price fell to $0.41, for a total market capitalization of some $10 million.

194. That fall, TetraLogic was acquired for $12 million in cash, payable to its creditors, not its shareholders.

195. In January 2016, TetraLogic announced that it had terminated Russell in a round of layoffs, effective April 19, 2016.

196. Having lost so much investor money so quickly in her last C-suite role put a question mark on Russell's career.

197. And indeed, Russell and Innocoll separated in November 2017. She has not taken up another job.

PLAINTIFFS' CLASS ACTION ALLEGATIONS

198. Plaintiffs bring this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of a class consisting of all persons other than defendants who acquired Innocoll common stock during the Class Period and who were damaged thereby (the "Class"). Excluded from the Class are Defendants, the officers and directors of Innocoll, members of the Individual Defendants' immediate families and their legal representatives, heirs, successors or assigns and any entity in which Officer or Director Defendants have or had a controlling interest.

199. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, Innocoll securities were actively traded on NASDAQ. While the exact number of Class members is unknown to Plaintiffs at this time and can be ascertained only through appropriate discovery, Plaintiffs believe that there are hundreds, if not thousands of members in the proposed Class.

200. Plaintiffs' claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by Defendants' wrongful conduct in violation of federal law that is complained of herein.

201. Plaintiffs will fairly and adequately protect the interests of the members of the Class and have retained counsel competent and experienced in class and securities litigation. Plaintiffs have no interests antagonistic to or in conflict with those of the Class.

202. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:

a. whether the Exchange Act was violated by Defendants' acts as alleged herein;

b. whether statements made by Defendants to the investing public during the Class Period misrepresented material facts about the financial condition and business Innocoll;

c. whether Defendants' public statements to the investing public during the Class Period omitted material facts necessary to make the statements made, in light of the circumstances under which they were made, not misleading;

d. whether the Defendants caused Innocoll to issue false and misleading SEC filings during the Class Period;

e. whether Defendants acted knowingly or recklessly in issuing false and SEC filing

f. whether the prices of Innocoll's securities during the Class Period were artificially inflated because of the Defendants' conduct complained of herein; and

g. whether the members of the Class have sustained damages and, if so, what is the proper measure of damages.

203. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and

burden of individual litigation make it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

204. Plaintiffs will rely, in part, upon the presumption of reliance established by the fraud-on-the-market doctrine in that:

a. Innocoll's shares and ADSs met the requirements for listing, and were listed and actively traded on the NASDAQ, a highly efficient and automated market;

b. as a regulated issuer, Innocoll filed periodic public reports with the SEC;

c. Innocoll regularly communicated with public investors via established market communication mechanisms, including through regular dissemination of press releases on the national circuits of major newswire services and through other wide-ranging public disclosures, such as communications with the financial press and other similar reporting services;

d. Innocoll was followed by at least 3 securities analysts employed by brokerage firms who wrote reports about the Company during the Class Period, including JMP Securities, Piper Jaffray, and Janney, and these reports were distributed to the sales force and certain customers of their respective brokerage firms. Each of these reports was publicly available and entered the public marketplace;

e. On average, 0.96% of Innocoll's outstanding shares and ADSs or shares were traded weekly, permitting a strong presumption of that its shares traded on an efficient market;

f. More than 50 market makers made a market in Innocoll's ADS; and

g. New company-specific information was rapidly reflected in Innocoll's stock price.

205. Based on the foregoing, the market for Innocoll securities promptly digested current information regarding Innocoll from all publicly available sources and reflected such information in the prices of the shares, and Plaintiffs and the members of the Class are entitled to a presumption of reliance upon the integrity of the market.

206. Alternatively, Plaintiffs and the members of the Class are entitled to the presumption of reliance established by the Supreme Court in *Affiliated Ute Citizens of the State of Utah v. United States*, 406 U.S. 128 (1972), as Defendants omitted material information in their Class Period statements in violation of a duty to disclose such information as detailed above.

FIRST CLAIM
Violation of Section 10(b) of
The Exchange Act and Rule 10b-5
Promulgated Thereunder Against All Defendants

207. Plaintiffs repeat and reallege each and every allegation contained above as if fully set forth herein.

208. During the Class Period, Defendants carried out a plan, scheme and course of conduct which was intended to and, throughout the Class Period, did: (i) deceive the investing public, including Plaintiffs and other Class members, as alleged herein; and (ii) cause Plaintiffs and other members of the Class to purchase Innocoll's securities at artificially inflated prices. In furtherance of this unlawful scheme, plan and course of conduct, defendants, and each of them, took the actions set forth herein.

209. Defendants (i) employed devices, schemes, and artifices to defraud; (ii) made untrue statements of material fact and/or omitted to state material facts necessary to make the

statements not misleading; and (iii) engaged in acts, practices, and a course of business which operated as a fraud and deceit upon the purchasers of the Company's securities in an effort to maintain artificially high market prices for Innocoll's securities in violation of Section 10(b) of the Exchange Act and Rule 10b-5. All Defendants are sued either as primary participants in the wrongful and illegal conduct charged herein or as controlling persons as alleged below.

210. Defendants, individually and in concert, directly and indirectly, by the use, means or instrumentalities of interstate commerce and/or of the mails, engaged and participated in a continuous course of conduct to conceal adverse material information about Innocoll's financial well-being and prospects, as specified herein.

211. These defendants employed devices, schemes and artifices to defraud, while in possession of material adverse non-public information and engaged in acts, practices, and a course of conduct as alleged herein in an effort to assure investors of Innocoll's value and performance and continued substantial growth, which included the making of, or the participation in the making of, untrue statements of material facts and/or omitting to state material facts necessary in order to make the statements made about Innocoll and its business operations and future prospects in light of the circumstances under which they were made, not misleading, as set forth more particularly herein, and engaged in transactions, practices and a course of business which operated as a fraud and deceit upon the purchasers of the Company's securities during the Class Period.

212. Each of the Individual Defendants' primary liability, and controlling person liability, arises from the following facts: (i) the Individual Defendants were high-level executives and/or directors at the Company during the Class Period and members of the Company's management team or had control thereof; (ii) each of these defendants, by virtue of their

responsibilities and activities as a senior officer and/or director of the Company, was privy to and participated in the creation, development and reporting of the Company's internal budgets, plans, projections and/or reports; (iii) each of these defendants enjoyed significant personal contact and familiarity with the other defendants and was advised of, and had access to, other members of the Company's management team, internal reports and other data and information about the Company's finances, operations, and sales at all relevant times; and (iv) each of these defendants was aware of the Company's dissemination of information to the investing public which they knew and/or recklessly disregarded was materially false and misleading.

213. The defendants had actual knowledge of the misrepresentations and/or omissions of material facts set forth herein, or acted with reckless disregard for the truth in that they failed to ascertain and to disclose such facts, even though such facts were available to them. Such defendants' material misrepresentations and/or omissions were done knowingly or recklessly and for the purpose and effect of concealing Innocoll's financial well-being and prospects from the investing public and supporting the artificially inflated price of its securities. As demonstrated by Defendants' overstatements and/or misstatements of the Company's business, operations, financial well-being, and prospects throughout the Class Period, Defendants, if they did not have actual knowledge of the misrepresentations and/or omissions alleged, were reckless in failing to obtain such knowledge by deliberately refraining from taking those steps necessary to discover whether those statements were false or misleading.

214. As a result of the dissemination of the materially false and/or misleading information and/or failure to disclose material facts, as set forth above, the market price of Innocoll's securities was artificially inflated during the Class Period. In ignorance of the fact that market prices of the Company's securities were artificially inflated, and relying directly or

indirectly on the false and misleading statements made by Defendants, or upon the integrity of the market in which the securities trades, and/or in the absence of material adverse information that was known to or recklessly disregarded by Defendants, but not disclosed in public statements by Defendants during the Class Period, Plaintiffs and the other members of the Class acquired Innocoll's securities during the Class Period at artificially high prices and were damaged thereby.

215. At the time of said misrepresentations and/or omissions, Plaintiffs and other members of the Class were ignorant of their falsity, and believed them to be true. Had Plaintiffs and the other members of the Class and the marketplace known the truth regarding the problems that Innocoll was experiencing, which were not disclosed by Defendants, Plaintiffs and other members of the Class would not have purchased or otherwise acquired their Innocoll securities, or, if they had acquired such securities during the Class Period, they would not have done so at the artificially inflated prices which they paid.

216. By virtue of the foregoing, Defendants have violated Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

217. As a direct and proximate result of Defendants' wrongful conduct, Plaintiffs and the other members of the Class suffered damages in connection with their respective purchases and sales of the Company's securities during the Class Period.

SECOND CLAIM
Violation of Section 20(a) of The Exchange Act Against the Individual Defendants

218. Plaintiffs repeat and reallege each and every allegation contained above as if fully set forth herein.

219. The Individual Defendants acted as controlling persons of Innocoll within the meaning of Section 20(a) of the Exchange Act as alleged herein. By virtue of their high-level positions, and their ownership and contractual rights, participation in and/or awareness of the Company's operations and/or intimate knowledge of the false financial statements filed by the Company with the SEC and disseminated to the investing public, the Individual Defendants had the power to influence and control and did influence and control, directly or indirectly, the decision-making of the Company, including the content and dissemination of the various statements which Plaintiffs contend are false and misleading. The Individual Defendants were provided with or had unlimited access to copies of the Company's reports, press releases, public filings and other statements alleged by Plaintiffs to be misleading prior to and/or shortly after these statements were issued and had the ability to prevent the issuance of the statements or cause the statements to be corrected.

220. In particular, each of these Defendants had direct and supervisory involvement in the day-to-day operations of the Company and, therefore, is presumed to have had the power to control or influence the particular transactions giving rise to the securities violations as alleged herein, and exercised the same.

221. As set forth above, Innocoll and the Individual Defendants each violated Section 10(b) and Rule 10b-5 by their acts and/or omissions as alleged in this Complaint. By virtue of their positions as controlling persons, the Individual Defendants are liable pursuant to Section 20(a) of the Exchange Act. As a direct and proximate result of Defendants' wrongful conduct, Plaintiffs and other members of the Class suffered damages in connection with their purchases of the Company's securities during the Class Period.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for relief and judgment, as follows:

(a) Determining that this action is a proper class action under Rule 23 of the Federal Rules of Civil Procedure;

(b) Awarding compensatory damages in favor of Plaintiffs and the other Class members against all Defendants, jointly and severally, for all damages sustained as a result of Defendants' wrongdoing, in an amount to be proven at trial, including interest thereon;

(c) Awarding Plaintiffs and the Class their reasonable costs and expenses incurred in this action, including counsel fees and expert fees; and

(d) Such other and further relief as the Court may deem just and proper.

JURY TRIAL DEMANDED

Plaintiffs hereby demand a trial by jury.

Dated: November 5, 2018

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on November 5, 2018, I filed the foregoing ***Consolidated Amended Class Action Complaint for Violation of the Federal Securities Laws*** with the Clerk of Court, which will send notification of such to all CM/ECF participants, and I had all parties, to be noticed, served by electronic mail.

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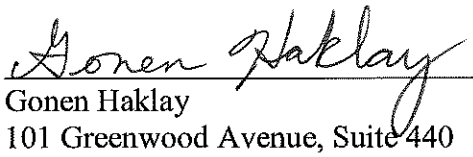

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